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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,595	07/25/2003	Richard A. Flavell	YU-P02-011	2979

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,595	FLAVELL ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, and 5-11, drawn to a polynucleotide encoding an IRAK-M kinase protein, a vector and cell comprising said polynucleotide, and a method of making the protein, classified in class 536, subclass 23.2.

II. Claims 3 and 4, drawn to an IRAK-M kinase protein, classified in class 435, subclass 194.

III. Claims 12 and 13, drawn to an IRAK-$M^{-/-}$ cell, classified in class 435, subclass 325.

IV. Claims 14-16, drawn to a method of identifying a compound that modulates the immune response of an individual, classified in class 435, subclass 7.24.

V. Claims 17 and 18, drawn to a method of anti-inflammatory treatment using a compound that modulates an IRAK-M protein, classified in class 514, subclass 1.

VI. Claims 19, 20, 22, and 23, drawn to a method of identifying an IRAK-M protein inhibitor by measuring cytokine production, classified in class 435, subclass 15.

VII. Claims 21 and 24, drawn to a method of identifying an IRAK-M protein inhibitor by measuring NF-kB activation, classified in class 435, subclass 15.

For Inventions VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VI and, if Invention VI is elected, one of Inventions (A)-(B), as indicated.

(A.) In cell culture

(B.) In vivo

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotide of Invention I is related to the polypeptide of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

The polynucleotide of Invention I is related to the cell of Invention III by virtue of being the cognate DNA necessary for the production of the cells. Although the DNA and cells are related, they are distinct inventions because they are physically and functionally distinct chemical entities and because the DNA can be used in another and materially different process

from the use for production of the cells, such as in a hybridization assay and for production of the encoded protein.

Inventions II and III are unrelated because the products of Inventions II and III are physically and functionally distinct chemical entities.

Inventions IV-VIII are independent because the methods of Inventions IV-VIII comprise different steps, utilize different products and/or produce different results.

The methods of Inventions VI and VII are related to the cell of Invention I as a product and process of using. The inventions are distinct because the cell can also be used for making the encoded protein.

Inventions IV and V are unrelated to Invention I because the methods of Inventions IV and V can neither use the polynucleotide of Invention I nor be used to make said polynucleotide.

Inventions I and IV-VII are unrelated because the methods of Inventions IV-VII can neither use the protein of Invention I nor be used to make said protein.

The methods of Inventions VI and VII are related to the cell of Invention III as a product and process of using. The inventions are distinct because the cell can also be used for examining the signal transduction mechanism mediated by IRKA-M protein.

Inventions IV and V are unrelated to Invention III because the methods of Inventions IV and V can neither use the cell of Invention III nor be used to make said cell.

Inventions IV-VII are independent because the methods of Inventions IV-VII comprises different steps, utilize different products, and/or produce different results.

A search for more than on of Inventions I-VII would be a burden on the Office for the following reasons.

The search of Invention I would not encompass a search for Invention II, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Invention II, class 435, subclass 194, would not encompass a search for Invention I, which would include searching class 536, subclass 23.2. Thus, a search of either Invention I or II would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

Because the products of Inventions I and III are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I and III would be a burden on the Office.

Because the products of Inventions II and III are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions II and III would be a burden on the Office.

Because the methods of Inventions IV-VI comprise different steps, utilize different products, and/or produce different results, a search for one said invention would not encompass a search for any other invention and searching all of Inventions IV-VI, or a subset thereof would be a burden on the Office.

A search for the products of Inventions I-III would not encompass a search for the methods of Inventions IV-VIII, or vice versa, because said methods are not the only methods of making and/or using said products. Thus, a search of any of Inventions I-III with any of Inventions IV-VIII would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different

classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Restriction between product and process claims has been required. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

Art Unit 1656